REMARKS

Status of the Claims

Upon entry of this Amendment, claims 27, 34-35, and 37-38 have been amended. Claims 1-26 and 39-45 have been canceled. Claims 27-38 remain pending in the application. No new matter has been introduced by the Amendment. Entry and consideration of this amendment are respectfully requested.

Interview

Applicants would like to thank the Examiner for the courtesy extended to the undersigned during the interview of April 22, 2003, in the above-captioned application.

Claim Rejections

1. Claims 42-45 are rejected under 35 U.S.C. § 112, first paragraph. Claims 39-45 have been canceled, thereby rendering this rejection moot.

2. Claims 28, 29 and 34-39 are rejected under 35 U.S.C. § 112, first paragraph, over allegations that the specification fails to describe the use of print molecules in embodiments other than for drugs which would be useful to prepare artificial antibodies. (Office Action, page 2).

Applicants respectfully traverse.

Applicants disclose "Antibodies ... are versatile reagents employed in numerous applications." (Specification, page 1). Further, the specification discloses that "[t]he invention

also provides for a method for determination of an organic molecule in a fluid sample". (Specification, page 3). Applicants disclose a broad invention which is utilized in embodiments other than for drugs or drug molecules.

The specification references an extensive list of scientific work, which enables a skilled artisan to choose appropriate print molecules in a variety of technologies. More specifically, the specification clearly states:

> The technique of molecular imprinting has attracted much attention in the last few years[6-8]. Recently, molecular imprinting has been developed to a stage of practical applications in enantomeric separations [11-15], in particular in the resolution of racemic drugs such as β-blockers[16].
>
> Furthermore, the technique has been applied to make synthetic enzymes [9,10].

(Specification, page 2).

Enantiomers, for one example, are a broad genus of compounds, many of which have uses which are not drug-related. Embodiments of the claimed invention when used in technologies directed toward enantiomers encompass non-drug embodiments. The manufacture of synthetic enzymes is another example of an embodiment not limited to drug molecules.

Further, Applicants request reconsideration of the context of the conclusion that "the claims include, for example, metals and metal complexes used as print molecules which would not be expected to have a disclosed immunoassay activity" (Office Action, page 2). Applicants note, Claim 35 does describe a competitive binding assay using a drug labeled with a label selected from a group including electrochemiluminescent compounds and gold. However, Applicants assert, the skilled artisan would understand that it is the drug portion which specifically binds to the artificial antibody leading to the desired immunoassay activity,

i.e., the ability to compete with the free drug for binding to the artificial antibody. None of the currently pending claims of the present invention are limited only to molecularly imprinted polymers using metals and metal complexes used as print molecules.

Any person skilled in the art to which this claimed invention pertains would have been fully enabled to practice Applicants' claimed invention by the disclosure of the specification and in view of the state of the art at the time of the filing of this application to select and use print molecules other than drugs to prepare artificial antibodies according to the claims of the subject application. (MPEP § 2164.05(b)).

The drug molecules presented in the examples of the present application are examples and not intended to limit the scope of the invention. One of ordinary skill in the art would be able to practice the presently claimed subject matter in a variety of technologies in view of the specification and the prior art without undue experimentation. The test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976). See also, MPEP § 2164.01. The fact that experimentation may be complex does not necessarily make it undue if those skilled in the art typically engage in such experimentation. *In re Certain Limited - Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm'n 1983); *M.I.T. v. A.B. Fortia*, 227 U.S.P.Q. 428 (Fed. Cir. 1985); *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). See also, MPEP § 2164.01.

Applicants submit that the "enablement" prong of the first paragraph of 35 U.S.C. §112 requires nothing more than objective enablement. Whether this is achieved by illustrative examples or by broad terminology is of no importance. *In re Marzocchi*, 169

U.S.P.Q. 367 (CCPA 1971). It is improper to reject claims on the ground that the specification does not support the claims when the terms of the claim are no broader than the broadest description of the invention in the specification and there is no reason to challenge the operativeness of the subject matter embraced by the claims. *Ex parte Altermatt*, 183 U.S.P.Q. 436 (POBA 1974).

Moreover, a patent does not teach, and preferably omits, what is well known in the art. *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984), See also, MPEP § 2164.01.

Favorable reconsideration and withdrawal of the rejection are earnestly solicited.

3. The Examiner's rejection of claims 37 and 38 (Office Action pages 2-3) as being improperly dependent from claim 34 is believed to be alleviated by amendment herein.

4. Claims 27, 28 and 34-38 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite over allegations of not reciting the moiety which is used in the "molecular imprint polymerization" method to form the "artificial antibody" (Office Action, page 3).

Applicants respectfully traverse.

In view of what was known in the art of molecular imprinting at the time of filing of this application, a skilled artisan would recognize the scope of the claimed artificial antibodies

regardless of the exact nature of the binding specificity or the print molecule used to make the material. The advance in molecular imprinting made by Applicants is disclosed in a manner sufficient to allow a skilled artisan to clearly understand what is claimed in this application. Artificial antibodies made of molecular imprinted cross-linked polymers can be prepared with binding specificities for a wide variety of target molecules. These polymers share, however, structural features such as the presence of tailored binding sites that conform to the structure of a print molecule.

Applicants urge the claims are sufficiently clear and definite to one of ordinary skill in the art when properly construed in view of the specification and what was known in the art at the relevant time. (MPEP Section 2173). The MPEP clearly states:

> In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000), see also *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished).

(MPEP 2173.02).

Favorable reconsideration and withdraw of the rejection are earnestly solicited.

5. The Examiner rejects claims 34 and 35 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite and confusing because "artificial antibodies of claim 27" recited in claim 34 are not limited to antibodies produced using "a drug molecule" (Office Action, page 3).

As discussed above, this application is not limited to "a drug molecule". Claim 27 is directed to the artificial antibodies produced by imprint polymerization. One subgenus of the genus of artificial antibodies of claim 27 encompasses those species able to interact with drugs or drug-like molecules.

Applicants urge that the claims 34 and 35 are sufficiently clear and definite to one of ordinary skill in the art when properly construed in view of the specification and what is known in the art. (MPEP Section 2173) Favorable reconsideration and withdraw of the rejection are earnestly solicited.

6. Applicants thank the Examiner for acknowledging Applicants' offer to file a Terminal Disclaimer, so that the term of this patent will not extend further than the term of U.S. Patent No. 5,959,050.

7. The Examiner maintains the rejection of claims 27-38 under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, obvious under 35 U.S.C. § 103(a) over Mosbach (U.S. Patent 5,110,833).

Applicants respectfully traverse the rejection under 35 U.S.C. § 102(b)/103(a).

Mosbach (U.S. Patent 5,110,833) does not explicitly disclose, teach or suggest the use of particles less than 5 microns or the advantages achieved using such particles.

Applicants assert that it was not until the present invention that "fines" (including particles less than 5 microns) were disclosed as being useful as injectible agents for *in vivo* use in the human body and for use in other embodiments such as homogeneous

immunoassays. Previously, such fines were "defined" and discarded. Applicants' disclosure teaches against this understood belief and recites "Another advantage with the fine particles in that they are more suitable for use in therapy and diagnostics" (Specification, page 4).

To clarify the record, the Applicants respectfully assert the Examiner's statement "contrary to Applicant's assertion that O'Shannessy, et. al., discards particles less than 25 micron ... " (Office Action, page 4) misconstrues, Applicants' response. Applicants stated "they also teach the removal and the discarding of any fine particles having a size much less than 25 μm." Applicants urge that the goal of defining in O'Shannessy is to obtain a reasonable particle size distribution around 25 micron. Consequently, particles less than 5 micron are removed from a solution and discarded as described in our previous response. Applicants refer to their response filed December 12, 2002, with regard to this matter.

Applicants respectfully submit a Declaration Under 37 CFR 1.132 by George B. Sigal, Ph.D., for the Examiner's consideration in support of the traverse presented herein.

Accordingly, Applicants maintain that Mosbach reference (U.S. Patent 5,110,833) does not disclose or suggest the claimed invention, and teaches away from the present invention for the reasons set forth in Applicant's previous response.

Therefore, the rejection of claims 27-38 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a) is improper and should be withdrawn.

CONCLUSION

In view of the above amendments and comments, the present application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

AUTHORIZATIONS:

A check for $950.00 is enclosed to cover the Three month extension fee. The Commissioner is also hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deport Account No. 13-4503, Order No. 2324-7028US1.

Respectfully submitted,
MORGAN & FINNEGAN, LLP

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By: _____
Eric G. Wright
Registration No. 48,045
(202) 857-7887 Telephone
(202) 857-7929 Facsimile

Correspondence Address:
MORGAN & FINNEGAN
345 Park Avenue
New York, New York 10154